DETAILED ACTION

The following is a Final Office action in response to communications received on 12/21/2011. Claims 1 and 40 have been amended. Claims 3-9, 15-17, 19-39, 42, 43, 49, 53, 54, 57, and 58 have been cancelled. Therefore, Claims 1, 2, 10-14, 18, 40, 41, 44-48, 50-52, 55, and 56 are currently pending and addressed below.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 2, 10, 12-14, 18, 51, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sahota 2003/0181973 in view of Brazzle et al. (" A Hysteresis-free platinum alloy flexure material for improved performance and reliability of MEMS

devices") in view of in view of Alt 6,767,360 or Brenneman 5,957,929 in view of Klumb et al. 6,572,648 in view of Cox 5,733,330.

3. Sahota teaches a stent and a delivery system that may be used in the brain (paragraph 41). The stent may be self-expandable or balloon expandable (paragraph 19) (Claim 1). The stent may be cut from a flat sheet or a tube of material (paragraph 72). Sahota also teaches that the stent may have end markers to enhance visibility (Fig. 7a) (Claim 14). Sahota further teaches the use of therapeutic coatings on the stent for drug delivery (paragraph 14) (Claim 12).

Sahota teaches the invention as claimed and as discussed above. However, Sahota does not disclose the use of an alloy made of about 75-80% platinum, 12-18% of rhodium, and 5-10% or ruthenium.

Brazzle teaches the use of Alloy 851 (a trade name for a platinum alloy having 79% platinum, 15% rhodium, and 6% ruthenium) in MEMS (microelectromechanical systems) as an ideal spring material.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent of Sahota with the alloy taught by Brazzle in order to gain desirable properties such as biocompatibility and extreme corrosion resistance as taught by Brazzle (abstract).

Sahota in view of Brazzle teaches the invention as claimed and as discussed above. However, Sahota in view of Brazzle does not explicitly teach a stent having a dimensional sidewall thickness. However, in paragraph [0052], Sahota also teaches that the stent thickness will vary dependent on the specified treatment. Alt '360 teaches

that a coronary stent has a sidewall thickness of 100 microns or less (col. 7, ll. 50-55) (Claims 1, 9, 54). Note, Brenneman 5957929 teaches intracranial stents having a thickness within the range as claimed also.

It would have been obvious to one of ordinary skill in the art at the time of the invention to form the stent of Sahota in view of Brazzle with the sidewall width of less than .0028 inches since the particular range is known to be established based upon the desired treatment in the coronary and/or intracranial environment with the stents as taught by Alt (col. 7, ll. 50-55) and/or Brenneman. It should be noted that limitations regarding the flexibility and expansion force of the stent are interpreted as functional limitations of the device and have limited patentable weight in the absence of differentiating structure. Since the composition of the alloy 851 as taught by Brazzle is within in range as claimed, examiner maintains that the physical properties (i.e. flexibility) of the two alloys would be essentially similar, if not, the same. The claimed wall thickness is taught by Alt and Brenneman. Applicant's specification, page 12, admits that "no special techniques are required in melting, casting, or working the alloy for fabrication of the stent." Therefore, absent any further claimed structural differences, the stent of Sahota as modified by Brazzle and Alt or Brenneman would possess similar, if not the same, physical properties.

Regarding Claims 51-53, applicant's specification has failed to set forth criticality and/or unexpected results directed to the various physical properties as claimed. It has been held that "the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set

of percentage ranges is the optimum combination of percentages." *In re Petersen.* **See MPEP 2144.05, Section II, Part A.**

Sahota in view of Brazzle in view of Alt or Brenneman teaches the device as claimed and as discussed above. Although implied, Sahota in view of Brazzle in view of Alt or Brenneman does not teach a stent surface to length ratio from 1.1-1.3 mm^2/mm.

Klumb teaches a stent graft having an average diameter to turns-width ratio of .1 to 1 to about 2.4 to 1 when in the expanded position (col. 6, ll. 14-21). It should be noted that the circumference (stent coverage) to turns ratio can be obtained by multiplying this ratio by *pi* (approx. 3.14) and would overlap the claimed ratio.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Sahota in view of Brazzle in view of Alt or Brenneman with the surface to length ratio of Klumb to make the stent useful when full surface coverage and reasonably higher outward radial force is desired as taught by Klumb (col. 6, ll. 9-11).

Sahota in view of Brazzle in view of Alt or Brenneman in view of Klum teaches the device as claimed and as discussed above. Although implied, Sahota in view of Brazzle in view of Alt or Brenneman in view of Klumb does not teach a *thickness and width* of less than 0.0028 inches.

Cox teaches that is known in the art for stent struts to have square cross-sectional areas (col. 2, ll. 53-54). A square cross section would result in a length and width less than .0028 inches as taught by Alt or Brenneman.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Sahota in view of Brazzle in view of Alt or Brenneman in view of Klumb with the square cross sectional areas for struts as taught by Cox since such a configuration is known and used in the art for stent struts.

4. Claims 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sahota 2003/0181973 in view of Brazzle et al. (" A Hysteresis-free platinum alloy flexure material for improved performance and reliability of MEMS devices") in view of in view of Alt 6,767,360 or Brenneman 5,957,929 in view of Klumb et al. 6,572,648 in view of Cox 5,733,330, as applied to Claim 10, further in view Alt 2004/0039438.

5. Sahota in view of Brazzle in view of Alt or Brenneman in view of Klumb in view of Cox teaches the invention as claimed and as discussed above. However, Sahota in view of Brazzle in view of Alt or Brenneman in view of Klumb in view of Cox does not teach a stent having iridium oxide or titanium nitrate coatings.

Alt '438 teaches a stent having a titanium nitrate or iridium oxide coating as well as therapeutic coatings (abstract) to inhibit tissue irritation and to deliver therapeutics to a local site in the body.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent of Sahota in view of Brazzle in view of Alt or Brenneman in view of Klumb in view of Cox with the coatings of Alt '438 in order to prevent tissue irritation and deliver drugs locally in the body.

6. Claims 40, 41, 44, 46-48, 50, 55, and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sahota 2003/0181973 of in view of Alt 6,767,360 or Brenneman 5,957,929 in view of Speidel ("Resistance to fatigue crack growth of the platinum metals") in view of Klumb et al. 6,572,648 in view of Cox 5,733,330.

7. Sahota in view of Alt or Brenneman teaches the invention as claimed and as discussed above. However, Sahota in view of Alt or Brenneman does not teach a stent made of an alloy that has a composition of about 65%-75% of platinum and 25-35% of rhodium.

Speidel teaches that a 70% platinum / 30% rhodium is a useful platinum alloy because rhodium has a higher resistance to fatigue crack growth than most other metals under cyclical stress (abstract).

It would have been obvious to modify the stent of Sahota in view of Alt or Brenneman with the alloy disclosed in Speidel in order to resist fatigue crack growth under cyclical loading as taught by Speidel (abstract) since it is known that stents undergo cyclical stress *in vivo* and manufacturers would be motivated to use alloys that would resist cracking. It should be noted that limitations regarding the flexibility of the stent are interpreted as functional limitations by the Examiner and hold limited patentable weight in the absence of differentiating structure or materials.

Regarding Claims 55 and 56, it has been held that "the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." *In re Petersen.* **See MPEP 2144.05, Section II, Part A.**

Sahota in view of Alt or Brenneman in view of Speidel teaches the device as claimed and as discussed above. Although implied, Sahota in view of Alt or Brenneman in view of Speidel does not teach a stent surface to length ratio from 1.1-1.3 mm^2/mm.

Klumb teaches a stent graft having an average diameter to turns-width ratio of .1 to 1 to about 2.4 to 1 when in the expanded position (col. 6, ll. 14-21). It should be noted that the circumference (stent coverage) to turns ratio can be obtained by multiplying this ratio by *pi* (approx. 3.14) and would overlap the claimed ratio.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Sahota in view of Alt or Brenneman in view of Speidel with the surface to length ratio of Klumb to make the stent useful when full surface coverage and reasonably higher outward radial force is desired as taught by Klumb (col. 6, ll. 9-11).

Sahota in view of Alt or Brenneman in view of Speidel in view of Klumb teaches the device as claimed and as discussed above. Although implied, Sahota in view of Alt or Brenneman in view of Speidel in view of Klumb does not teach a *thickness and width* of less than 0.0028 inches.

Cox teaches that is known in the art for stent struts to have square cross-sectional areas (col. 2, ll. 53-54). A square cross section would result in a length and width less than .0028 inches as taught by Alt or Brenneman.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Sahota in view of Alt or Brenneman in view of Speidel

in view of Klumb with the square cross sectional areas for struts as taught by Cox since such a configuration is known and used in the art for stent struts.

8. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sahota 2003/0181973 in view of Alt 6,767,360 or Brenneman 5,957,929 in view of Speidel ("Resistance to fatigue crack growth of the platinum metals") in view of Klumb et al. 6,572,648 in view of Cox 5,733,330. as applied to Claim 44, further in view Alt 2004/0039438.

9. Sahota in view of Alt or Brenneman in view of Speidel in view of Klumb in view of Cox teaches the invention as claimed and as discussed above. However, Sahota in view of Alt or Brenneman in view of Speidel in view of Klumb in view of Cox does not teach a stent having iridium oxide or titanium nitrate coatings.

Alt '438 teaches a stent having a titanium nitrate or iridium oxide coating as well as therapeutic coatings (abstract) to inhibit tissue irritation and to deliver therapeutics to a local site in the body.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent of Sahota in view of Alt or Brenneman in view of Speidel in view of Klumb in view of Cox with the coatings of Alt '438 in order to prevent tissue irritation and deliver drugs locally in the body.

Response to Arguments

1. Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JASON-DENNIS STEWART whose telephone number is (571)270-3080. The examiner can normally be reached on M-F (alt Fridays off) 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Sweet can be reached on (571)272-4761. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to: TC3700_Workgroup_D_Inquiries@uspto.gov.

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